JUN 2 6 2000

K001569

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

INFINITY™ Amylase Reagent, Procedures 580/568

Sigma Diagnostics INFINITY™ Glucose Reagent is intended for in vitro diagnostic use only, for the quantitative determination of α-amylase in human serum, plasma,or urine on both automated and manual systems.

α-Amylase is derived mainly from the salivary glands and the exocrine pancreas. α-Amylase catalyses the hydrolysis of α-1 –4 glucosidic linkages of starch and other related polysaccharides to produce maltose and other oligosaccharides. The enzyme is a relatively small molecule which is rapidly cleared by the kidneys and excreted in the urine. α-Amylase is most frequently measured in the diagnosis of acute pancreatitis when serum levels may be grossly elevated.

The INFINITY Amlyase Reagent utilizes ethylidine-pNP-G7 (E-pNP-G7) as the substrate, The use of ethylidine p[revents exo-enzymes from breaking down the substreate so in the absence of α-amylase, no color change is observed. Once the substrate has been cleaved by α-amylase, the smaller fragments can be acted upon by α-glucosidase, which causes the ultimate release of the chromo[hore. The rate of formation of pNP is proportional to the α-amylase activity present in the sample and is measured by the increase in absorbance at 405 nm.

The Sigma Diagnostics INFINITY™ Amylase Reagents (Procedure No. 580/568) are substantially equivalent to, and are the same products as the TRACE Scientific Amylase Reagents cleared by the FDA as K972997.

The use of plasma is supported by correlation studies (N=126) with Sigma Diagnostics Amylase Reagent, Procedure No. 577 (K913858) on a Hitachi 717. The resulting regression equation (INFINITY Amylase = 0.967 (Amylase 577) + 1.693) demonstrates substantial equivalence.

Submitted May 18, 2000 by

William Gilbert
Sigma Diagnostics
545 South Ewing
St. Louis, MO 63103
314 286-6693

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 6 2000

William R. Gilbert, Ph.D.
Manager, Scientific Affairs
Sigma Diagnostics, Inc.
545 South Ewing Avenue
St. Louis, Missouri 63103

Re: K001569
Trade Name: INFINITY™ Amylase Reagent
Regulatory Class: II
Product Code: JFJ
Dated: May 17, 2000
Received: May 19, 2000

Dear Dr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: INFINITY™ Amylase Reagent

Indications For Use:

The Sigma Diagnostics INFINITY™ Amylase Reagent is a device intended to measure the activity of the enzyme amylase in serum, plasma and urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001569

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR **Over-The-Counter Use** ___
(Per 21 CFR 801.109)